Bayer HealthCare
Diabetes Care Division

SEP 11 2006

510(k) SUMMARY

Ascensia® *CONTOUR*® Blood Glucose Monitoring System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K062058.

Prepared:	August 4, 2006
Submitter:	Bayer HealthCare, Diabetes Care Division
Address:	430 South Beiger Street Mishawaka, IN 46544 Phone (574) 262-7152; FAX (574) 262 6945
Contact:	Roger Sonnenburg, Regulatory Affairs Manager
Device:	Trade/Proprietary Name: Ascensia® *CONTOUR*® Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Meter
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75 LFR, Glucose Dehydrogenase, Glucose
Predicate Device:	Ascensia® *CONTOUR*® Diabetes Care System, K023657
Device Description:	The Ascensia® *CONTOUR*® Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The system contains a blood glucose meter, a bottle of strips, a bottle of normal control solution, a lancing device and lancets, and instructions for use.

Intended Use:	The Shogun Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The Shogun Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. The Shogun Blood Glucose Monitoring System is indicated for use with capillary, venous, and arterial whole blood samples and neonatal blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.
Technological Characteristics:	There were no changes to the fundamental scientific technology.
Comparison to Predicate device:	The modifications to the device encompass meter design changes, software changes, and labeling changes. There has been no change to the intended use, operating principle, or functionality of the device.
Assessment of Performance:	An evaluation of the Ascensia® *CONTOUR*® Blood Glucose Monitoring System was studied in the laboratory and in a clinical setting by persons with diabetes. The results were compared to results from the original Ascensia® *CONTOUR*® Blood Glucose Monitoring System and to a laboratory method. The studies showed equivalent performance with the original Ascensia® *CONTOUR*® Blood Glucose Monitoring System.
Conclusion:	The results of the laboratory and clinical evaluations of the Shogun Blood Glucose Monitoring System demonstrated that the device produces blood glucose results that are substantially equivalent to results obtained on the predicate device. Therefore, the system with the modified meter is as safe and effective as the original system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Roger Sonnenburg
Bayer Healthcare LLC
Diabetes Care Division
430 South Beiger Street
Mishawaka, IN 46544

SEP 11 2006

Re: k062058
Trade/Device Name: Ascensia® CONTOUR ® Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Roger Sonnenburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

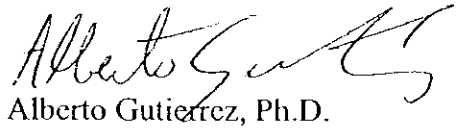
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062058

Device Name: Ascensia® *CONTOUR*® Blood Glucose Monitoring System

Indications For Use: The Ascensia® *CONTOUR*® Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The Ascensia® *CONTOUR*® Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

The Ascensia® *CONTOUR*® Blood Glucose Monitoring System is indicated for use with capillary, venous, and arterial whole blood samples and neonatal blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel.

The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional) K062058